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APPLICATION NO.	FIL	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,076 07/03/2003		Leigh H. English	MECO:218-1 11792.0218.DVU	8919	
45607	7590	04/04/2006		EXAM	INER
HOWREY LLP				KUBELIK, ANNE R	
C/O IP DOC	KETING I	DEPARTMENT			
2941 FAIRVIEW PARK DRIVE SUITE 200				ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22042				1638	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)					
		10/614,076	ENGLISH ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Anne R. Kubelik	1638					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1)⊠	☑ Responsive to communication(s) filed on <u>19 December 2005 and 27 February 2006</u> .							
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.							
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.					
Dispositi	ion of Claims							
5)□ 6)⊠ 7)□	Claim(s) 38-49 is/are pending in the application 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 38-49 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	n from consideration.						
Applicati	on Papers							
9) 🗌	The specification is objected to by the Examiner	•						
	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
Attachment	• •							
1) Unotice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date								
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   Statement   St								

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 February 2006 has been entered.

- 2. Claims 38-49 are pending.
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 112

4. Claims 38-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 23 September 2005, as applied to claims 38-46, due to Applicant's amendment of the claims. Applicant's arguments filed 19 December 2005 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "one or more point mutations ... Gln348 to arginine" in claim 38, lines 5-11, claim 39, lines 14-18 and claim 46, lines 2-5, the phrase "one or more point mutations ... Lys189 to Gly" in claim 44, lines 6-8, and the phrase "one or more amino acids is selected ... lysine or

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valine" in claim 40, lines 24-7. Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

Applicant urges that support for Arg162 to His was found in the amendment to Table 2 filed 3/1/05 (response pg 6).

There was no amendment filed on that date; however, the amendment filed 6/30/05 does provide support as the amendment corrects an error. Amendments before final are entered as a matter of course. This portion of the rejection is withdrawn.

Applicant points to places in the specification that recite "one or more mutations" (response pg 6-7).

This is not found persuasive, as there is no support for the particular combinations of mutations recited in the claims, either before the current amendment or after, nor is there any support for mixing and matching the mutations in Table 2.

Applicant urges that the mutations "Leu158 to Arg ... Lys189 to Gly" are all in or near the  $\alpha$  helix 4 region, and there are examples in the specification that have at least one of these (response pg 7-8).

This is not found persuasive. There is no support in the specification for the particular combination of one of those mutations in combination with any or all of the further mutations. Each of the cited examples only provide support for the particular combination of substitutions made in those variants.

Applicant urges that support for mutations of Asp165 to Gly and one or more of the mutations at amino acids 311, 33 and 317 is found in the specification and Table 2 (response pg 8).

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This is not found persuasive, as there is no support for the particular mutations recited in the claims, nor is there any support in the specification for mixing and matching the mutations in Table 2. Each of 11082, 11098, 11081 and 11084 only provide support for the particular combination of substitutions made in those variants, and some of these variants have mutations other than those recited in the claim.

Applicant urges that the phrase "one or more amino acids is selected ... lysine or valine" in claim 40, lines 24-7 is supported by pg 31, lines 8-12 and various variants (response pg 9).

This is not found persuasive because there is no support in the specification for mixing and matching the particular mutations and substitutions. None of the recited variants, for example, has Asn313 to valine or Glu317 to alanine or to valine with any substitution in Ser311.

5. Claims 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 47 lacks antecedent basis for the limitation "said one or more amino acid replacement" in lines 1-2.

## Conclusion

- 6. No claim is allowed.
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D. March 29, 2006

ANNE KUBELIK, PH.D. PRIMARY EXAMINER